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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,228	02/26/2004	Wallis Wiremu Farraday	357089/0150	7967

7590 10/05/2009
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EXAMINER

JACKSON, BRANDON LEE

ART UNIT	PAPER NUMBER
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3772

MAIL DATE	DELIVERY MODE
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10/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/789,228

Applicant(s)

FARRADAY, WALLIS WIREMU

Examiner

BRANDON JACKSON

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to amendments/arguments filed 6/2/2009.
Currently, claims 12-22 are pending in the instant application.

Response to Arguments

Applicant's arguments filed 6/2/2009 have been fully considered but they are not persuasive.

With respect to the Declarations of Wallis Faraday under 37 C.F.R. 1.132, it has been noted that Mr. Farraday has tremendous amount of skill in the art of orthopedic devices from his 32 years of working in the field. However, Mr. Farraday's expertise cannot overcome a lack of a written description to support the Applicant's claim limitation "...providing a non-weight bearing post-operative protection to a limb within ten days from the amputation of such limb..." Mr. Farraday points to Applicant's statement of the dressing being intended for amputees that "have no potential for ambulating" as support for the non-weight bearing portion of the claim limitation. However, the mere fact that a dressing may be worn by a person that cannot walk does not mean the device is necessarily non-weight bearing. For example, an amputee could be wearing a prosthetic leg that could be used for ambulation, but never actually use it while walking or standing; therefore, the fact that the person is not ambulatory or not using the device for ambulation does not mean it is non-weight bearing. Moreover, ambulation refers to walking, not standing, therefore, Applicant's written description does not preclude the invention from being used by a standing amputee.

Mr. Farraday also suggests that the claim limitation of the dressing being applied within 10 days of amputation was contemplated by Applicant's original disclosure because Applicant discloses the dressing is for immediate use after amputation. Though it may be possible that Applicant's dressing can be applied within 10 days or even a day of amputation, the written description has not support for the arbitrary number of 10 days. In order to use a specific number of days, such as 10, the written disclosure must specifically state the range or else it is new matter.

With respect to applicant's arguments that none of the prior art of record provides a non-weight bearing post-operative protection, all of the pieces of art obviously y could be non-weight bearing when the device is worn be a person who is sitting or lying flat.

With respect to applicant's argument that none of the prior art of record discloses a dressing that could be applied within 10 days of amputation, Caspers teaches a sleeve to be worn over a residual limb. Caspers does not teach a specific amount of time that must be waited before the sleeve may be worn and there is nothing to suggest that it could not be worn within 10 days of amputation. Caspers further discloses that a goal of the Caspers device is to treat new amputations (col. 1, lines 17-23).

Applicant argues the Schon device teaches away from a custom molded orthotic. However, the Schon reference was used for the teaching of a distal pad, not a custom molding. The teaching of a custom molded device was already provided by Caspers.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant specification does not provide sufficient support for the amendments. The only mentioning of the application of the post operative protection within ten days is in paragraph 005, however, it pertains to prior art, not to Applicant's claimed invention. Applicant's specification also does not disclose that the post-operative protection is non-weight bearing, only that that method enhances rehabilitation to accelerate the maturity of the residual limb for weight and non-weight bearing purposes. This pertains to the limb, not to whether the protection device is bearing weight or not.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12 -15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caspers (US Patent 5,571,208) in view of Kania (US Patent 5,830,237), Vanden (US Patent Application Publication 2003/0114783), and Schon et al. (US Patent 6,368,357). Caspers discloses a method of dressing a post-operative residual limb (12) comprising applying a liner (90) on a residual limb (12), covering a the liner (90) with a protective covering (50), placing a spacer (42) around the residual limb (12) prior to applying the cast forming gauze (54); wherein the spacer is remove prior to using the device. It is well known in the art that the plaster of Paris used is gauze with a material that hardens after water is applied. The soft tissue or residual muscle tissue is shaped before the gauze solidifies (col. 6, lines 21-37). It would be obvious to one of ordinary skill in the art at the time of the invention to cut the cast proximate the spacer in order for the cast to fit the use without having sharp edges, this is well known in the art. The dressing obviously could be applied to the limb within 10 days of amputation in order to begin the healing process and protect the residual tissue from infection. Also, the dressing is not weight bearing when the artificial limb (104) is not applied. Caspers fails to disclose the method including a liner that is a thermo plastic gel, the step of placing a distal pad on a

distal end of the residual limb above the liner, cutting the cast along its periphery to permit removal, and securing the cast with one or more securing mechanism.

Kania teaches a removable post operative limb dressing comprising a thermoplastic gel liner (cushion liner, Figure 7A) and a protective covering over the liner (fabric liner, column 6, lines 20-25),. Wherein the gel line would obviously compress and contain a post-operative residual limb tissue of a limb because of its snug fit about the limb. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to replace the Caspers' liner with the thermo plastic gel liner as taught by Kania, because it is easy to manipulate and provides the user with more comfort.

Vanden teaches a method of making a hinged orthopedic device (1) comprising cutting a finished device lengthwise and hinging the device (par. 0005) forming two portions (fig. 3A), and a securing mechanism (7, 8, 9). The device cut should be a moldable material, such as plaster of paris. The device is for the arm, however it is analogous to all amputated limbs. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Casper/Kania to include the step of cutting the device to permit removal, hinging it, and securing it with a strap, as taught by Vanden, because it would allow easy application and removal of the device.

Schon teaches a therapeutic device (200) for amputees comprising a distal pad (210) at the distal end of the residual limb. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify device of Caspers/Kania/Vanden to have a distal pad, as taught by Schon, in order to provide the

user with more comfort and support in that weight bearing area. It would also be obvious to one of ordinary skill in the art to cut the device proximate the distal pad when cutting its periphery.

Claims 16 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caspers (US Patent 5,571,208) in view of Kania (US Patent 5,830,237) and Vanden (US Patent Application Publication 2003/0114783). Caspers discloses a method of dressing a post-operative residual limb (12) comprising applying a liner (90) on a residual limb (12), covering a the liner (90) with a protective covering (50), placing a spacer (42) around the residual limb (12) prior to applying the cast forming gauze (54); wherein the spacer is remove prior to using the device. It is well known in the art that the plaster of Paris used is gauze with a material that hardens after water is applied. The soft tissue or residual muscle tissue is shaped before the gauze solidifies (col. 6, lines 21-37). It would be obvious to one of ordinary skill in the art at the time of the invention to cut the cast proximate the spacer in order for the cast to fit the use without having sharp edges, this is well known in the art. Caspers fails to disclose the liner is thermo plastic gel, cutting the cast along its periphery to permit removal, and securing the cast with one or more securing mechanism.

Kania teaches a removable post operative limb dressing comprising a thermoplastic gel liner (cushion liner, Figure 7A) and a protective covering over the liner (fabric liner, column 6, lines 20-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to replace the Caspers liner with the

thermo plastic gel liner as taught by Kania, because it is easy to manipulate and provides the user with more comfort.

Vanden teaches a method of making a hinged orthopedic device (1) comprising cutting a finished device lengthwise and hinging the device (par. 0005) forming two portions (fig. 3A), and a securing mechanism (7, 8, 9). The device cut should be a moldable material, such as plaster of paris. The device is for the arm; however it is analogous to all amputated limbs. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Caspers/Kania to include the step of cutting the device to permit removal, hinging it, and securing it with a strap, as taught by Vanden, because it would allow easy application and removal of the device.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caspers/Kania/Vanden as applied to claim 16 above, and further in view of Schon et al. (US Patent 6,368,357). Caspers/Kania/Vanden fails to disclose placing a pad proximate a joint and cutting the cast proximate the pad. However, Schon teaches a therapeutic device (200) for amputees comprising a distal pad (210) at the distal end of the residual limb. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Caspers/Kania/Vanden device to have a distal pad, as taught by Schon, in order to provide the user with more comfort and support in that weight bearing area. It would also be obvious to one of ordinary skill in the art to cut the device proximate the distal pad when cutting its periphery.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON JACKSON whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brandon Jackson/
Examiner, Art Unit 3772

BLJ

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772